UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,227	11/26/2001	Alan M. Fogelman	407T-899210US	9958

22798 7590 01/13/2005

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
JIANG, SHAOJIA ANNA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,227	FOGELMAN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on September 13, 2004 wherein claims 14-81 are cancelled; claims 1-13 have been amended.

Currently, claims 1-13 are pending in this application.

Note that claim 13 as amended now is directed to the non-elected invention wherein the subject matter is recited in claim 16 as originally filed and now cancelled; thus claim 13 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, of record in the previous Office Action dated March 10, 2004.

Claims 1-12 as amended now are examined on the merits herein.

Applicant's remarks filed September 13, 2004 with respect to the rejection of claim 4 made under 35 U.S.C. 112 second paragraph for the indefinite recitation of record stated in the Office Action dated March 10, 2004 have been fully considered and found persuasive to remove the rejection since one of ordinary skill in the art would recognize that the recited fatty acids are moieties in phospholipids. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsia et al. (5,231,090, of record).

Hsia et al. discloses that applicants' claimed known compounds, i.e., synthetic phospholipids, phosphatidylcholine and phosphatidylserine when administered in effective amounts are useful in methods of increasing the ratio of HDL to LDL by enhancing serum HDL cholesterol and lowering serum LDL cholesterol, and treating atherosclerosis in a mammal (see col.2 lines 42-63; claims 1-14). In particular, the testing data in Hsia et al. show that the serum HDL level was raised significantly after the administration of phospholipids composition to rabbits (see the table at Fig. 4 and Fig. 3; col.3 line 57-60). At column 1, lines 55-60 teaches that phospholipids were administered intravenously and topically and resulted in the resolution of atherosclerotic lesions. Examples II and III illustrate the administration of phospholipids to humans are effective in treating phospholipids.

Claim 2 drawn to a phospholipid that is a phospholipid that inhibits upregulation of an MKP-I gene is deemed to be inherent in the teachings set forth above since applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method steps in Hsia et al. are same as the claimed herein. An explanation of why that

effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

The phospholipids, phosphatidylcholine, phosphaidylserine, (applicants' claim 3) are taught at column 2, lines 56-63; claims 6 and 7 also read on the teachings at column 2, lines 56-63 wherein it is taught that the claimed phopholipids can be combined.

The mode of administration as claimed in claims 8 and 10 are taught in thereference as injection and in the form of a gel liquid for topical application (Example I-II at col.3-4).

Thus, Hsia et al. anticipates Claims 1-3, 6-8, and 10-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia et al. (5,231,090) in view of Bertilli (4,684,520 of record).

The same disclosure of Hsai et al. has been discussed above.

Hsai does not teach the oral administration of said pholsolipids.

However, one of ordinary skill in the art would be motivated to administer said phospholipids orally since Bertilli at column 2, lines 47 to column 3, line 19 teach that phospholipids can be administered orally.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia et al. (5,231,090) in view of Bertilli (4,684,520, of record).

Hsai does not expressly teach employing an analogue of the particular pholsolipid in the methods of treatment therein.

Bertilli teaches that certain phospholipids and derivatives including glycerol-phospholipids (see col.1 line 19-27; col.5 lines 44-57) possess same functions and usefulness in treating atherosclerosis as phospholipids (see column 5, line 44-56). Thus, glycerol-phospholipids are interpreted as analogs of applicants' claimed active agent in claim 5, also known as DMPC.

One of ordinary skill in the ad would have been motivated to use an analogue of applicants' claimed compound to treat atherosclerosis, i.e., by enhancing serum HDL cholesterol and/or lowering serum LDL cholesterol, in a mammal since glycerol-phospholipids, analogs of applicants' claimed compound, are known to treat atherosclerosis.

Response to Argument

Applicant's arguments filed September 13, 2004 with respect to the rejections of record in the previous Office Action March 10, 2004 have been fully considered but are

not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicants assert that Hsia et al. fails to disclose "having fatty acids in the sn-1 and sn-2 positions that are the same and that range in length from 3 to 24 carbons". However, Applicants are reminded that the instant claim 1 as drafted clearly recites a group consisting of phosphatidyl choline, phosphatidyl serine,....or phosphatidyl inositol, having fatty acids in the sn-1 and sn-2 positions that are the same and that range in length from 3 to 24 carbons", which is interpreted as a Markush group of agents. Thus, the agent "having fatty acids in the sn-1 and sn-2 positions that are the same and that range in length from 3 to 24 carbons" is one of Markush agents, not limiting any agents before, e.g., not limiting phosphatidyl choline.

Moreover, the source of an active agent or compound whether from natural or synthetic is not given any patentable weight unless they are structurally and materially distinct and different, for example the structure of phosphatidyl choline is same whether it is derived from nature or synthesized by man. Applicants own journal article (not prior art) has been considered but not found persuasive to overcome the rejections of record since the disclosure of Hsia et al. clearly anticipates the claimed invention, in particular the objective factual evidence, the testing data disclosed by Hsia et al. clearly anticipate the claimed method herein, as pointed out above in the 102(b) rejection.

Further, the instant claims are not limited to DMPC as a single agent but also an analogue thereof. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret

what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example. In this case, as discussed above, glycerol-phospholipids are interpreted as analogs of DMPC recited in claim 5 herein.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
January 11, 2005